NEUROTHERM RADIO FREQUENCY LESION GENERATOR
MODEL JK3

OPERATORS MANUAL

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EC DECLARATION OF CONFORMITY
YEAR 2000 CONFORMITY
PULSED RF DETAILS

Using the NeuroTherm Stimulation Test Kit

Introduction

There are times when the cannula and thermocouples look to be properly positioned in the patient but the patient does not feel any stimulation.

The Stimulation Test Kit provides a positive test that the electrode and RF lesion generator are operating correctly. The test can be performed within the sterile field.

Preparation

Ensure that the Stimulator Test Kit is kept sterile and always available.

Contents
- Red cable
- Circular test block
- Blue sterilising tray
- Instructions for use

Sterelisation Instructions

After use the Stimulation Test Kit should be cleaned as per institutional policy using any normally available cleansing agent.

Sterilize by autoclave as for porous materials. Maximum permitted temperature 140°C.

Check Thermocouple

When the thermocouple is plugged into the JK3 the red LED labelled THERMOCOUPLE will turn green. When inserted into the cannula the temperature reading on the JK3 in TEST or in LESION mode will read between 35° and 38°C.

Check the Reference Plate

Ensure that the reference plate is properly connected. With the thermocouple and cannula in place in the patient check the IMPEDANCE.

Check the Stimulation

Plug the red test lead into the JK3 and the other end into the test round block. Place the test block on the sterile trolley.

Switch the JK3 into STIMULATOIN mode, set to 100 Hz or 3 Hz, turn up the amplitude and note the meter increases up to 2 Volts approximately.

Remove the sterile thermocouple from the patient, the cannula can stay in place, and touch the end of the thermocouple onto the sterile block.

With the amplitude turned up a buzz (100 HZ) or a tick (3 Hz) will be heard.

This is proof positive that the stimulation voltage is actually being delivered to the tip of the cannula.

Repositioning the Electrode

If all is correct with the machine and electrodes then the position of the cannula is suspect. Continue to reposition until the patient feels the stimulation.

If a satisfactory threshold cannot be found turn up the stimulation voltage to 0.5 Volt (or 1 Volt) and keep the stimulation on while the needle is slowly moved around. Ensure an assistant is ready to turn the amplitude down or off as soon as stimulation is felt as it can be painful for the patient. When stimulation is felt properly test for the sensory threshold turning up from zero.

1. GENERAL INTRODUCTION

The Neurotherm Radio Frequency Lesion Generator has been designed to offer the full range of features required by practioners for pain relief clinic work.

The front panel has been ergonomically designed and allows the clinician direct manipulation of the controls via sterilisable knobs. Each functional effect of the device is defined within it's own discrete area.

It is designed for safe use in a low light x-ray theatre environment.

Analogue meters are used to facilitate immediate visual interpretation of temperature, rf current and rf voltage, and digital displays are used for impedance, stimulate voltage and lesion time.

The lesion generator has full electronic interlocking to prevent accidental switching to lesion power and stimulation voltage.

The internal settings of the machine have been factory set and should not be adjusted except by approved technicians authorised by the company.

The machine is designed for use with NeuroTherm Thermocouple Probes. The use of probes from other manufacturers could give serious errors in the temperature reading and may compromise the safety of the patient, and would negate the warranty.

2. TECHNICAL DATA

SIZE

Width	400 mm (15.7")
Height	172 mm (6.8")
Depth	430 mm (16.9")

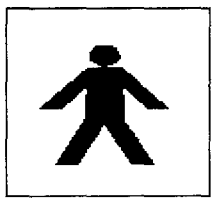
WEIGHT

8.9Kg	(19.5lbs)

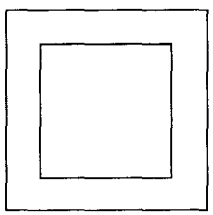
ELECTRICAL

UK	230 volt 50 Hz Fused 1 Ampere on live and neutral
USA	110 volt 60Hz Fused 2 Ampere on live and Neutral

The power supply is built to Class II standard. The instrument is not connected to mains earth. (Class II BF).



TYPE BF EQUIPMENT



CLASS II EQUIPMENT

STANDARDS This instrument complies with BS 5724 and IEC 601-1 and MDD 93/42/EEC Class IIB

IMPEDANCE

Measuring frequency	53 KHz approx
Digital Display	0-2000 Ohms (in 1 ohm steps)
Accuracy	± 20%
Digital Display Reading	Digital display reads biological impedance
Self Test	500 ±5% Ohm

STIMULATOR

Voltage Amplitude	Continuously variable between 0 - 2 volts. The voltage supplied is displayed on the Digital Meter in 0.01 Volt steps.
Accuracy	± 5% of reading
Pulse Rates	3 or 100 Hz (pulses per second)
Pulse Width	1mSec
Waveform	Biphasic pulses. Negative pulse leading
Lamp Indicator	Green LED flashes at pulse rate of 3 Hz and is continuous at a pulse rate of 100 Hz. Indicator only lights when output is present
Test Facility	When Needle is touched on Test Block sounder will indicate that output is present

RF LESION POWER (Continuous RF Power or Pulsed RF Power)

RF frequency	300 kHz (±10%) sine wave
Power Output	Continuously variable. Maximum power output 8 Watts into 200 Ohms. (Cordotomy socket 0-1watt)
Pulsed RF Power	The set Power Output is applied for 20mSec every 500 mSec
Voltmeter	0 - 40 RF Volts
Self Test	Into 200 Ohm dummy load resistance built into machine
Lamp Indicators	Amber LED flashes when this facility is in circuit and power is active.

LESION TIMER

Range	Timer counts down from preset times of 60, 90, 120 or 180 seconds. Timer stops when lesion power is turned off. Timer can be restarted when lesion power is established. Turning the Function . Switch to any position other than "LESION" resets the time to its set point.
Time Indicator	Clock Indicates amount of time remaining for lesioning. At the end of the preset period alarm tone sounds and power is removed from the needle. Tone can be stopped by turning the Lesion Power to the OFF position. Timer resets to set point for the next lesion.
Audible Indicator	A one second "tick" indicates the clock is running.

TEMPERATURE MONITOR

Meter Range	30°C to 100°C

PROBES

Use only NeuroTherm Thermocouple probes	No individual adjustment necessary

LAMP INDICATOR

LED shows Green with thermocouple connected or Red with thermocouple disconnected or faulty.

SAFETY FEATURES

Safety Cut Out	Lesion Power is automatically reduced if temperature reaches set limit as determined by temperature switch, 70°C, 80°C, 90°C. Lesion Power will automatically increase again once the temperature of the tip of the probe drops below the set limit. On Pulsed RF temperature limit is 42°C.
Safety Interlock	Lesion Power cannot be delivered unless the RF Power Control is first set to the OFF position, this prevents any accidental application of the RF power. If the lesion power is selected and power control is on, a high pitched warning tone is given out. This warning tone is approximately 80dB at 1metre.

EARTH LEAKAGE DATA

Tests carried out as per IEC 601-1

	TYPICAL VALUE	MAXIMUM ALLOWABLE
Enclosure leakage current normal	2.5 microamps	100 microamps
Single Fault condition	10 microamps	500 microamps
Patient leakage current	2.5 microamps	100 microamps
Single Fault	10 microamps	500 microamps
Patient leakage current with applied main	10 microamps	100 microamps
Leakage-Mains applied to Output	10 microamps	5 milliamps

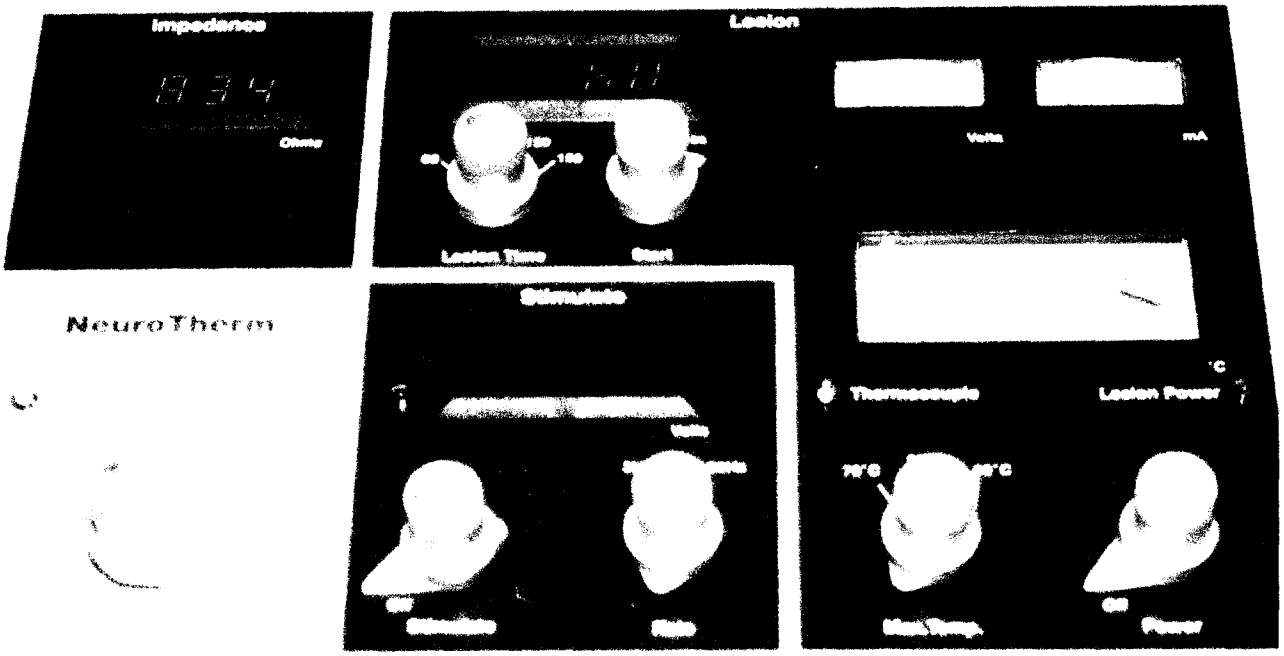
ACCESSORIES SUPPLIED

7	Sterilisable Knobs	
3	Sterile Temperature Probes	1 x 5 cm R55.405 1 x 10 cm R55.406 1 x 15 cm R55.407
1	Mains Lead	
1	Dispersive Plate Lead	
1	Test Block	
1	Pack of 10 Dispersive Plates	
5	5 cm Cannula R55.510	
5	10 cm Cannula R55.511	
5	15 cm Cannula R55.512	
3	Sterilisable Boxes for probes	
1	Operators Manual	
1	Service Manual	
1	Basic Operating Procedures	

3. DESCRIPTION OF CONTROLS

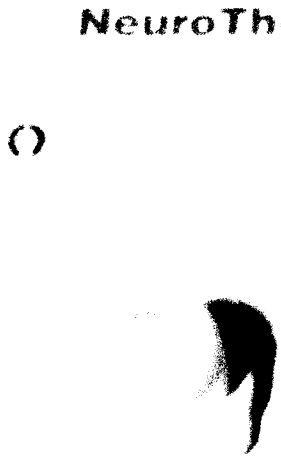
3.1 OPERATING PANEL LAYOUT

The front panel of the lesion generator machine is segmented into four panels



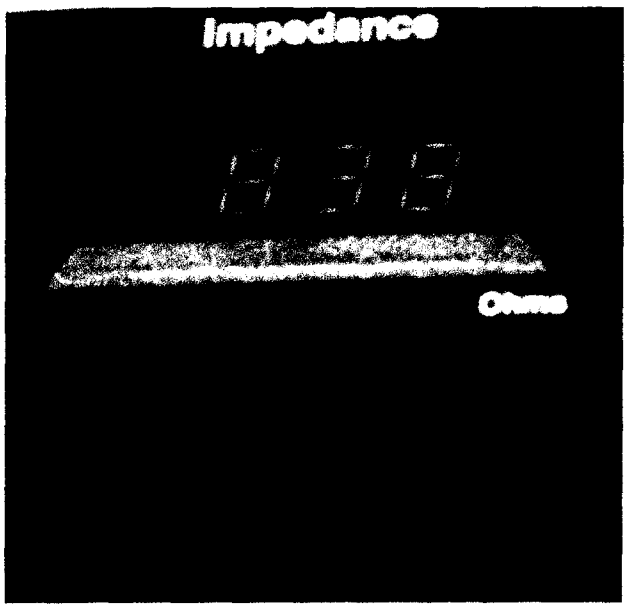
1. SELECT MODE
2. IMPEDANCE METER
3. STIMULATE CONTROLS
4. LESION POWER CONTROLS

3.1.1 SELECT MODE SWITCH



OFF	Indicates the machine is inoperative. The Mains Power is controlled by a switch on the rear.
TEST	For testing the Radio Frequency output, timer and impedance functions. This procedure is described in Section 4. CHECK AND TEST PROCEDURES.
IMPEDANCE	Measures the impedance in Ohms, between the tip of the lesion probe and the dispersive plate.
STIMULATE	Controls voltage between 0 and 2.0 Volts at rate of either 3Hz or 100Hz.
LESION	For applying continuous Radio Frequency power to the Lesion Probe.
PULSED RF	For applying Pulsed RF power to the Lesion Probe

3.1.2 IMPEDANCE METER



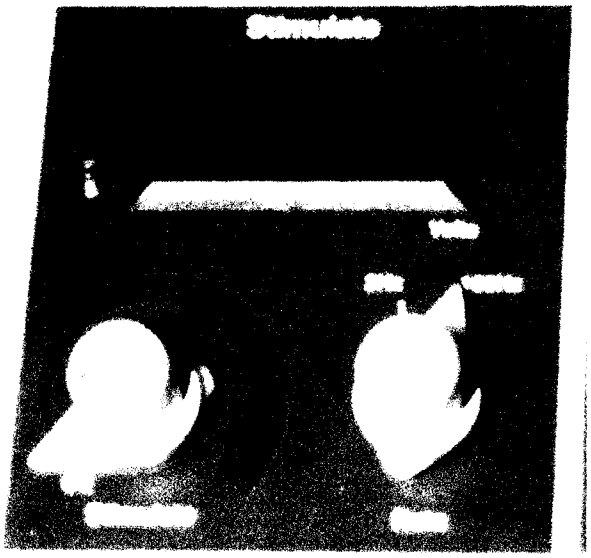
The digital display shows the impedance measurement between the tip of the Lesion Probe and the dispersive plate. The readout is in Ohms.

It should be noted that this measurement is of biological impedance.

Impedance measurement is only made when Lesion power is off.

In the test mode a measurement is displayed of a 500 Ohm resistor built into the machine. The meter display is switched off if lesion power is activated.

3.1.3 STIMULATE SECTION



The Stimulate Voltage control knob is used to adjust the Stimulation Amplitude. Up to 2.0 volts can be applied, the voltage supplied is displayed on the digital meter.

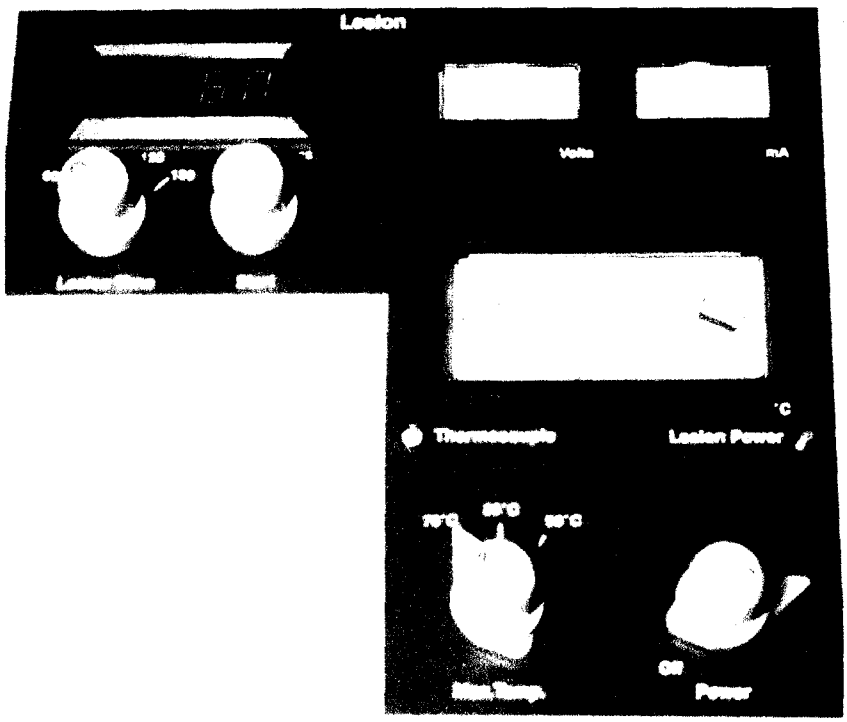
If when this function is selected the Stimulate Voltage Control is not in its OFF position, no stimulate voltage will be supplied to the probe. The Stimulate Voltage Control needs to be turned to the OFF position before power can be applied.

A green LED indicates that the STIMULATE output is active.

When a Stimulate Rate of 3 Hz has been selected the LED will flash at 3Hz and when 100 Hz has been selected the LED is lit constantly.

A Test Facility is provided so that when the thermocouple is touched on the Test Block, a sounder will indicate that output is present.

3.1.4 LESION POWER SECTION



A LESION POWER CONTROL

This controls the supply of radio frequency power to the lesioning probe. The power is variable from 0 - 8 Watts.

The Lesion Power Control must initially be in the OFF position otherwise no lesion power can be delivered and an alarm will sound. The select mode switch must be in the LESION position.

A flashing yellow LED above the Lesioning Power Control knob indicates that lesion power is being delivered. The amount of lesion power is indicated on the radio frequency voltage and current meters in Volts and Milliamps. A rise in the probe temperature is shown on the temperature meter.

A Maximum Temperature Switch enables temperature limits of 70°C, 80°C, or 90°C to be selected.

The temperature Limits are Safety Limits and should not be used to control the temperature of the lesion except when being continuously observed by the operator.

B RADIO FREQUENCY VOLTAGE AND CURRENT METERS

These analogue meters show the amount of electrical voltage and current being delivered to the lesion site. They are calibrated to show Root Mean Square (RMS) values.

C TEMPERATURE METER

This analogue meter shows the temperature at the lesion site once the select mode has been turned to the LESION (or Pulsed RF) position. The meter is calibrated in degrees celsius, with an accuracy of ± 1°C.

A Red/green LED indicates if the termocouple is present and operating correctly. Green – correct, Red – Fault/Disconnected.

D TIMER DISPLAY

The timer is enabled only if the Select Mode Switch is in the Lesion, Pulsed RF or Test position. Once the Lesion power is being applied the Start Timer Switch is activated by a small clockwise twist.

The timer will then start counting down from the set time displayed until it reaches zero at which point power is removed from the probe and a warning tone is heard. This sound can be stopped by turning the Lesion Power Control off. During a lesion the timer can be stopped at any time by turning the Lesion Power Control off and can be restarted from its previous time once power is re-established.

At the end of the timing period the timer resets to its set time ready for the next lesion.

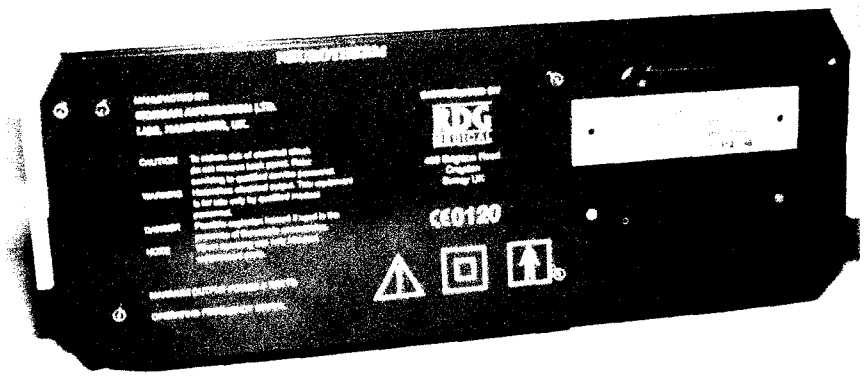
Set time periods of 60, 90, 120, 180 seconds can be selected by the "Set Time" switch.

E WHEN PULSED RF IS SELECTED

The Selct Mode Switch must be in the Pulsed RF position.

The Lesion Power control supplies pulsed radio frequency power to the lesioning probe. For this function the limiting temperature is automatically set to 42°C

3.2 BACK PANEL LAYOUT



1 MAINS ON/OFF SWITCH

This is a rocker type switch, combined with an I.E.C connector socket with twin `in-line' anti-surge fuses in a single unit to BS 4265.

2 MAINS IEC CONNECTOR

The three pin plug of the mains lead must be pushed into this socket. This cannot be done incorrectly i.e with the live and neutral reversed because of the orientation of the unused earth pin.

3 FUSES

The Neurotherm is protected by two in-line fuses, one on the live line and one on the neutral line. These fuses are located to the right hand side of the mains on/off switch. The fuses are 20 mm Anti Surge to BS 4265. 1 amp for 230V supply, 2 amp for 110V supply.

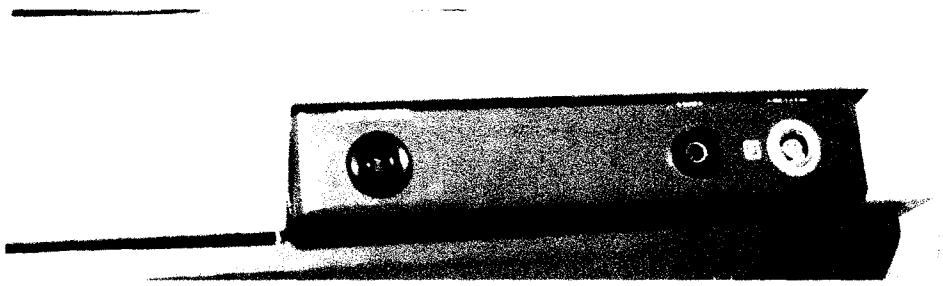
4 CONTACT ADDRESS

If the NeuroTherm requires a routine service or in the unlikely event of the machine malfunctioning, the contact address and telephone number of RDG Medical is shown in Section 7.1.

5 VENTILATION APERTURE

This is to ensure air circulation within the Generator machine and should not be blocked.

3.3 FRONT PANEL LAYOUT



1. LEFT HAND 4MM SOCKET

This socket is for the lead of the Dispersive Patient Plate, which should be of at least 200 square centimetres (21 square inches)

2. MIDDLE 4MM SOCKET

This socket is for the Test Block.

3. RIGHT HAND 4 WAY LEMO SOCKET

This socket is for the connection of the probe to the lesion generator and for carrying the thermocouple signal.

4. CHECK AND TEST PROCEDURES

These should be carried out before each session

CHECK	
1 The Mains Switch is OFF	This switch is located at the rear of the generator
2 Select Mode Switch is in the OFF position	
3 Stimulate Volts Control is set at OFF	
4 Lesion Power Control knob is turned FULLY ANTI-CLOCKWISE	
TEST	
5 Connect the Mains Power lead to the machine	
6 Turn Mains Switch ON	The Mains Green LED on the front Panel will light up.
7 Connect the NeuroTherm probe to the right hand LEMO socket	The right hand LEMO socket is located on the front panel of the generator
8 Turn the Select Mode Switch to the Test position	This will connect the Radio Frequency output to dummy load of 200 ohms inside the machine. An interlock relay will prevent Radio Frequency power from being applied to the patient. The Impedance meter will indicate approximately 500 Ohms.
9 Check that the temperature meter is active by holding the tip of the probe between sterile gloved fingertips	There should be a slight movement of the meter needle.
10 Turn the Lesion Power control CLOCKWISE	As the control is turned clockwise, the rising power being dissipated by the dummy load will be shown on the RF Current and Voltage meters, a reading near to full scale should be indicated by both meters when the control is fully clockwise. When lesion power is applied the impedance function is automatically switched off.
11 Start the clock and test that the time starts to count down	
12 Turn the Select Mode Switch to the OFF Position	TESTING OF THE GENERATOR IS NOW COMPLETE

5. STERILISATION PROCEDURES

Needles are supplied sterilised, double wrapped and for single patient use.

The probes, leads and plugs must be sterilised by autoclaving before re-use .

6. LESION PROCEDURES

Apply a suitable dispersive electrode to the patient and connect this to the left hand socket on the generator.

The left hand 4mm protected socket is located on the very front of the generator. Ensure that a dispersive electrode of the right surface area (not less than 100 sq cm) is correctly applied to the chosen site. Check that the clip on the lead that connects the dispersive plate to the generator does not come into contact with the patient.

Turn the Mains Switch **ON** and leave for two minutes to stabilise.

THE PROCEDURE CAN NOW BE STARTED. FROM NOW ON YOU ARE IN STERILE MODE

Carefully fit the set of 7 sterile knobs onto the controls of the instrument and plug the sterile Thermocouple lead into the 'Lemo' socket on the front panel.

Make sure the knobs are well located onto the plastic shafts. Turn them anti-clockwise until they lock.

Plug Test Block into the socket located between the Dispersive Socket and Thermocouple Socket

Make sure the Select Mode Switch is turned to the **TEST** position and the Lesion Power Switch is turned fully anti-clockwise to the **OFF** position.

If section 10 of the **CHECK AND TEST PROCEDURES** has been omitted it should now be done. The Thermocouple probe is checked by holding it's tip between sterile gloved fingertips. A slight movement of the Temperature meter needle should occur.

Make sure that the Volts indicator on the Stimulate Section is set at zero.

IMPEDANCE MEASUREMENT

When the needle positions are satisfactory, switch to impedance mode, insert the probe into the needle and measure the impedance

A reading of 400 to 1000 Ohms is correct. If the reading is greater than 1500 Ohms check the probe, lead and dispersive plate connections. If the reading is below 100 Ohms change the probe and intermediate lead.

STIMULATE

Set Stimulate Voltage to zero

Turn to stimulate mode

Set the stimulate rate at 3 Hz or 100 Hz as required and note responses and differentials.

If clinician is satisfied that the needles are in the correct position, and the patient responds satisfactorily to the stimulation, take X-rays for the patient's records. Inject local analgesic or administer light General Anaesthetic as appropriate. The patient is now ready for lesioning.

If it is necessary to check that stimulation output is present, then touch the thermocouple on the Test Block, and a sounder will indicate output is present.

Turn Select Mode switch to the **LESION** position

If the lesion power switch has been accidently left on, an alarm will sound and no power will be delivered. In this case the Lesion Power Switch must be turned to the **OFF** position then the Lesioning procedure can recommence.

Turn the Lesion Power Control **CLOCKWISE**

The Lesion Power LED will flash

When the required temperature is reached, shown on the temperature meter, start the timer by a small clockwise movement of the Start Timer controls

The timer will start counting down from the set value until it reaches zero, at which point Lesion power will be switched off and the timer will reset to its set value. If during a procedure power is turned off the clock will stop. The timer can be restarted by turning power back on and operating the Start Timer Control.

At the end of the required time for Lesioning turn the Lesion Power Control fully **ANTI-CLOCKWISE** to the **OFF** position until a click is heard.

Note
The Maximum temperature Switch sets Safety Limits at 70°, 80°, 90°. If Lesioning at these temperatures, turn the Lesion Power Control to achieve the required Lesion Temperature.

If no further lesion power is required, turn Lesion Power Switch off and Select Mode Switch to OFF

Do not turn Lesion Power Control fully clockwise and rely on the Safety Limit to control the temperature.

If using RF Pulse mode the RF Voltage and Current Meters will 'kick' every ½ second.

7. MAINTENANCE

The **CHECK AND TEST PROCEDURE** described in Section 4 should be routinely performed each time the Lesion Generator is used. A periodic full service on an annual basis is recommended.

Maintenance should only be carried out by authorised personnel.

In the event of the NeuroTherm Radio Frequency Lesion Generator malfunctioning, you should immediately call.

RDG MEDICAL
429 Brighton Road
Croydon Surrey
CR2 6EU

Tel: 0181-660-4374
Fax: 0181-660-9417

8. ACCEPTANCE TESTING

JK3 NeuroTherm Machine

Mains 'on' Green LED will be lit
The Select Mode Switch should be set to 'LESION'
Stimulate Voltage Control to OFF
Rate to 3Hz
Max.Temp to 70°C
Lesion Power to 'OFF'

Electrical Safety Analyser

If an Automatic or Manual Electrical Safety Analyser is used, the following settings must be used

Machine Class: Class II Type BF

To test the various leads of the output, only use the outer two plugs

1 Dispersive plug (4mm socket)
2 Active Plug (Lemo socket)

There is no specified EARTH REFERENCE POINT as the output is floating and could possibly induce operational errors. If an earthing point is needed, attach onto any of the four hexagonol bolts on the rear of the machine.

Morgan
The **Intelligent** **Application** of **Technology**

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EC DECLARATION OF CONFORMITY

Morgan Automation Ltd. declares that the apparatus known as :-

Neurotherm – Model JK3

is in conformity with the following Standards and Requirements :-

BS EN 60601-1-2 : 1993
ISO 13485 : 1996
BS EN 46001 : 1994
BS 5724 Section 2:3 : 1983
BS 5724 Section 1:1 :1992 IEC 601-1-1:1992
Directive 93/42/EEC

Is subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS Yarsley International Certification Services Ltd.

Signed :-..... Date : 3-12-98

Name ...H.M. CLARKE..... (Technical Director)

Ref: TECHFILE/NTDEC.doc

RDG MEDICAL
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YEAR 2000 CONFORMITY

16th December 1997

General Statement

This is to confirm that the NeuroTherm RF Lesion Generator does not contain a date sensitive microprocessor or date sensitive programme.

ROD GEMMELL
Managing Director

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